

SEP - 3 2004

K041520

**Mantra International Ltd.**

**P.O. Box 800**

**Oxford, OH 45056**

**Tel: (740) 549-5703**

**FAX: (740) 549-5701**

**510(k) Summary**

**Contact Person:** Brent Reider

**Date of Preparation:** March 12, 2004

**Trade Name:** Mantra TENS Model NT3

**Common Name:** Transcutaneous Nerve Stimulator

**Classification Name:** Stimulator, Nerve, Transcutaneous, for Pain Relief

**Product Code:** GZJ

**Regulation Class:** 2

**Regulation Number:** 882.5890

**Description of the Device:** The Mantra TENS Model NT3 is a Dual Channel Transcutaneous Nerve Stimulator (TENS).

**Intended Use:** The device is intended for the symptomatic relief of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain.

**Technical Characteristics:** The technical characteristics of the Mantra TENS Model NT3 are identical to the predicate device. The unit is battery operated and produces a biphasic asymmetrical waveform. This is a digital unit, which provides twelve pre-set programs and two user-customized programs. The electrodes consist of hydrogel in contact with the skin, a carbon conductor, and a nonwoven backing material.

There are three modes of operation: Conventional TENS, Burst Mode, and Modulation.

The Conventional TENS mode enables the user to select any rate between 2 Hz – 200 Hz, and a pulse width between 50 – 300 microseconds. This is the most frequently used of the three modes. The most common selection is 80 Hz with a 200 microsecond pulse width.

The burst mode is comparable to the low rate TENS technique except that each low rate pulse is substituted for by a short BURST of 9 pulses [200 microseconds] at 150 Hz.

The modulation mode is achieved by continuously cycling the pulse width and rate.

**Substantial Equivalence:** This product is substantially equivalent to the Classic TENS™ manufactured by Care Rehab, McLean, Virginia (K020437).

Substantial equivalence is based upon:

- The Mantra TENS Model NT3 has the same indications for use as the predicate device.
- The Mantra TENS Model NT3 has equivalent technological characteristics and instructions for use, as compared to the predicate device.
- The device meets the mandatory performance standards.
- The biocompatibility of the electrodes has been established.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mantra International Ltd.  
C/o Mr. Robert B. Spertell  
RBS Technologies, LLC  
10235 Glade Avenue  
Chatsworth, California 91311

Re: K041520

Trade/Device Name: Mantra TENS Model NT3  
Regulation Number: 21 CFR 882.5890  
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief  
Regulatory Class: II  
Product Code: GZJ  
Dated: March 9, 2004  
Received: June 7, 2004

Dear Mr. Spertell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

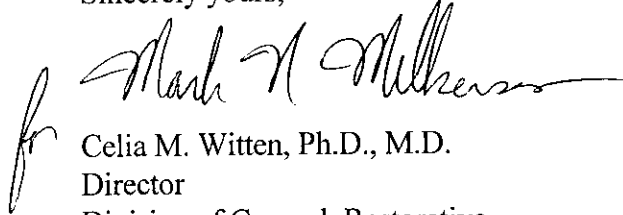
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 -- Mr. Robert B. Spertell

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end. To the left of the signature is a small, handwritten "for" in cursive.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known):

Device Name: Mantra TENS Model NT3

**Indications for Use:** TENS is used for symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter-Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Concurrence of CDRH, Office of Device E

*Mark H. Milken*

**(Division Sign-Off)**

**Director of General Representative**

## Division of General, Restorative, and Neurological Devices

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